CABINET FOR HEALTH AND FAMILY SERVICES

Office of Health Policy

(Amended After Comments)

900 KAR 5:020. State Health Plan for facilities and services.

RELATES TO: KRS 216B.010-216B.130

STATUTORY AUTHORITY: KRS 194A.030, 194A.050(1), 216B.010, 216B.015(27), 216B.040(2)(a)2a

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)2.a requires the cabinet to promulgate an administrative regulation, updated annually, to establish the State Health Plan. The State Health Plan is a critical element of the certificate of need process for which the cabinet is given responsibility in KRS Chapter 216B. This administrative regulation establishes the State Health Plan for facilities and services.

Section 1. The 2010 – 2012 State Health Plan [~~2009 Update to the 2007-2009 State Health Plan as amended June 9, 2009~~] shall be used to:

(1) Review a certificate of need application pursuant to KRS 216B.040; and

(2) Determine whether a substantial change to a health service has occurred pursuant to KRS 216B.015(28)(a) and 216B.061(1)(d).

Section 2. Incorporation by Reference. (1) The 2010 – 2012 State Health Plan **as amended July 15, 2010** [~~2009 Update to the State Health Plan as amended June 2, 2009~~] is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Division of Certificate of Need, 275 East Main Street, fourth floor, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

900 KAR 5:020

REVIEWED:

Carrie Banahan, Executive Director — Date
Office of Health Policy

APPROVED:

Janie Miller, Secretary — Date
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 5:020 (Amended After Comments)
Contact Person: Carrie Banahan or Shane P. O'Donley, (502) 564-9589

1. Provide a brief summary of:

   (a) What this administrative regulation does: This administrative regulation incorporates by reference the State Health Plan, which is used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040.
   (b) The necessity of this administrative regulation: KRS 216B.015(27) requires that the State Health Plan be prepared triennially and updated annually. This administrative regulation incorporates the 2010 - 2012 State Health Plan by reference.
   (c) How this administrative regulation conforms to the content of the authorizing statutes: The preparation of the State Health Plan is required by KRS 216B.
   (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: The preparation of the State Health Plan is required by KRS 216B.

2. If this is an amendment to an existing administrative regulation, provide a brief summary of:

   (a) How the amendment will change this existing administrative regulation: The amendment will update the 2010 - 2012 State Health Plan.
   (b) The necessity of the amendment to this administrative regulation: KRS 216B.015(27) requires that the State Health Plan be prepared triennially. The last triennial State Health Plan was prepared in 2009, so the next triennial plan is being prepared for 2010-2012.
   (c) How the amendment conforms to the content of the authorizing statutes: The amendment carries out the requirement of KRS 216B.015(27) which requires that the State Health Plan be prepared triennially.
   (d) How the amendment will assist in the effective administration of the statutes: This amendment will provide an updated State Health Plan for purposes of certificate of need review.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect health care providers governed by the Certificate of Need law, citizens who use health care in Kentucky, health planners in the Certificate

of Need Program, and local communities that plan for, use, or develop community health care facilities.

4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

   (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The modifications will apply to potential Certificate of Need applicants for Diagnostic and Therapeutic Equipment and Procedures.
   (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to entities to comply with this amendment.
   (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The criteria for applicants proposing to establish fixed site diagnostic cardiac catheterization has been made less stringent, applicants may now propose to expand their existing diagnostic cardiac catheterization service to also provide primary (emergency) angioplasty services on a two (2) year trial basis, and applicants may propose to provide comprehensive (diagnostic and therapeutic) cardiac catheterization services without a comprehensive cardiac surgical program (including open-heart surgery) within the facility. These changes may increase access to cardiac catheterization services to areas of the state that do not currently have these services.

5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

   (a) Initially: No cost
   (b) On a continuing basis: No cost

6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No funding is necessary since there is no cost to implementing this administrative regulation.

7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.

8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.

9. TIERING: Is tiering applied? (Explain why or why not)
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The "equal protection" and "due process" clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 5:020 (Amended After Comments)
Contact Person: Carrie Banahan or Shane O'Donley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

   Yes ___X___ No _____

   If yes, complete questions 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment may impact any government owned, controlled or proposed healthcare facilities or services.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.015(27) requires that the State Health Plan be prepared triennially and updated annually. This administrative regulation incorporates the 2010 – 2012 State Health Plan by reference.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None.

   (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No impact to revenues.

   (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenues will be generated to state or local government.

   (c) How much will it cost to administer this program for the first year? None.

   (d) How much will it cost to administer this program for subsequent years? None.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None
Expenditures (+/-): None
Other Explanation: None

STATEMENT OF CONSIDERATION RELATING TO 900 KAR 5:020
Office of Health Policy
Amended After Comments

(1) A public hearing on 900 KAR 5:020 was scheduled on 05/21/2010 at 9:00 a.m. No one attended the hearing, however, written comments were received during the public comment period.

(2) The following people submitted written comments via the public comment process:

NAME AND TITLE	AGENCY/ORGANIZATION/ENTITY/OTHER
Mary Jo Bean	Norton Healthcare
Bruce Begley	Methodist Hospital
John Dubis	St. Elizabeth Medical Center
Kelly Elkins	Saint Joseph Health System
Nancy Galvagni	Kentucky Hospital Association
Kevin Halter	Our Lady of Bellefonte Hospital
Lisa Hinkle	on behalf of Nurses Registry
Fred Jackson	King's Daughters Medical Center
Barry Papinia	Georgetown Community Hospital
Hollie Phillips	Appalachian Regional Healthcare
Michelle Sanborn	Children's Alliance
Heidi Schissler Lanham	Protection & Advocacy
Andy Sears	Baptist Healthcare System

(3)The following people from the promulgating administrative body responded to the written comments:

NAME AND TITLE	
Carrie Banahan	Executive Director, Office of Health Policy
Shane O'Donley	Policy Advisor

SUMMARY OF COMMENTS AND AGENCY RESPONSE

(1) Subject Matter: Cardiac Catheterization (Diagnostic Only)

(a) Comment: Barry Papinia, on behalf of Georgetown Community Hospital, requests that the Cabinet shrink the planning area to only include the proposed county where the applicant is located.

(b) Response: The Cabinet has considered this comment and while we do not agree that the planning area should only include the county where the applicant is located, we have revised to state that the planning area should include the county of the proposed cardiac catheterization program and all contiguous counties.

(c) Comment: Mary Jo Bean, on behalf of Norton Healthcare, requests that the Cabinet retain the former definition outlining how procedures are counted.

(d) Response: The Cabinet has considered this comment and determined that uniform administrative claims data that is currently submitted by all hospitals to the Office of Health Policy is a more accurate source of data to determine the number of cardiac catheterization procedures performed at each facility. The Cabinet will use the administrative claims data to produce a *Kentucky Annual Administrative Claims Data Report* which will replace the *Kentucky Annual Hospital Utilization and Services Report* as the source cited by the State Health Plan to determine the number of cardiac catheterization procedures performed by each facility.

(e) Comment: Mary Jo Bean, on behalf of Norton Healthcare, Barry Papinia, on behalf of Georgetown Community Hospital, Kelly Elkins, on behalf of Saint Joseph Health System and Nancy Galvagni on behalf of the Kentucky Hospital Association requests that the Cabinet eliminate the requirement that a hospital seeking to establish a cardiac catheterization service employ a full time cardiologist.

(f) Response: The Cabinet has considered this comment and has amended the State Health Plan to state that the applicant has established a cardiology program as evidenced by the availability of at least two (2) board certified cardiologist with medical staff privileges at the applicant's hospital.

(g) Comment: Kelly Elkins, on behalf of Saint Joseph Health System, requests that the Cabinet eliminate review criterion 1.C.

(h) Response: The Cabinet has considered this comment and has made corresponding changes to the State Health Plan.

(i) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, requests that:

1. The Cabinet utilize "cases" rather than "procedures";
2. Limit approval to acute care hospitals which are located in a planning region that does not already have existing diagnostic cardiac catheterization services; and
3. Delete the requirement that physicians perform at least 150 diagnostic procedures annually.

(j) Response: The Cabinet has considered this comment with the following consideration:

1. Please see comment C and corresponding response. By utilizing administrative claims data, procedures and cases will have the same meaning.
2. The Cabinet disagrees with the comment as it would limit competition and be more restrictive than previous criteria by not allowing any new diagnostic catheterizations laboratories even if utilization or population increased in a planning area.
3. The Cabinet agrees with this comment and has made corresponding changes to the State Health Plan.

(k) Comment: Hollie Phillips, on behalf of ARH, is supportive of the Cabinet's amendments.

(l) Response: The Cabinet has considered this comment and appreciates the support for the proposed State Health Plan.

(m) Comment: John Dubis, on behalf of St. Elizabeth Healthcare, is supportive of the Kentucky Hospital Associations recommendations with regard to primary angioplasty.

(n) Response: Please refer to the Cabinet's above response (j).

(2) Subject Matter: Cardiac Catheterization (Diagnostic w/Primary PCI)

(a) Comment: Mary Jo Bean, on behalf of Norton Healthcare and Nancy Galvagni, on behalf of the Kentucky Hospital Association, requests that the Cabinet ensure that an approval will not result in the reduction of primary PCI procedures performed at existing programs in the planning area to fall below 36 annual procedures.

(b) Response: The Cabinet has considered this comment and has made corresponding changes to the State Health Plan.

(c) Comment: Kelly Elkins, on behalf of Saint Joseph Health System, requests that:

1. The Cabinet clarify that the tertiary hospital be licensed by

the Commonwealth of Kentucky,

2. Include the same minimum volume of surgeries by the collaborating hospital regardless of their designation as a tertiary hospital or university hospital and clarify that the minimum volume requirement for "cardiac" surgeries means "open heart" surgeries as reported in the most recently published *Kentucky Annual Hospital Utilization and Services Report.*

(d) Response: The Cabinet has considered these comments and

1. Disagrees with this comment and does not wish to limit collaborating tertiary hospitals to only those licensed by the Commonwealth of Kentucky, as hospitals located close to other states borders may be utilized as tertiary hospitals.
2. Agrees with the comment and rather than treating university hospitals and tertiary hospitals differently, the State Health Plan has been amended to require that all collaborating tertiary hospitals must simply have an active comprehensive cardiac surgical program within the facility.

(e) Comment: Fred Jackson, on behalf of King's Daughters Medical Center, requests that the Cabinet prohibit new Primary PCI programs from being established if the applicant is within 30 vehicular minutes from an existing angioplasty program.

(f) Response: The Cabinet has considered this comment but believes that such modifications are not warranted at this time. The primary purpose of allowing the establishment of a primary PCI program is to improve access to these services during an emergency situation. Requiring a patient to be transferred up to an additional thirty (30) vehicular miles could impose unnecessary risk to their safety and well-being.

(g) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, requests that:

1. The Cabinet delete the requirement for a 2 year trial, and lower the volume threshold from 300 diagnostic procedures to either 200 diagnostic procedures or 200 diagnostic cases,
2. Eliminate the requirement for collaborating hospitals to have performed 300 cardiac surgeries and instead require only that "the facility have a current, signed collaboration agreement with a tertiary hospital that has on-site open heart surgery",
3. Require physicians performing primary PCI to perform at least 75 PCI procedures annually and clarify that the program director must have performed at least 500 PCI

procedures during their entire career. Both Bruce Begley, on behalf of Methodist Hospital and Andy Sears, on behalf of Baptist Healthcare System, support these recommendations.

(h) Response: The Cabinet has considered these comments and concludes the following:

1. The Cabinet believes that an entity should only be approved to establish a cardiac catheterization program on a trial basis and also operate a diagnostic cardiac catheterization lab at sufficient levels. These standards are consistent with the recommendations contained in the Cabinet's recently sponsored statistical report entitled *Kentucky Pilot Project for Primary PCI without Onsite CABG* published by the University of Louisville's Cardiovascular Innovation Institute. Therefore, the Cabinet will not amend the State Health Plan to eliminate the trial or lower the diagnostic cardiac catheterization volume threshold to a level below what was recommended in the above referenced report. Doing so could have a detrimental effect of the health, safety and welfare of potential patients.
2. The State Health Plan will be amended to include the recommended changes.
3. The State Health plan will be amended to include the recommended changes.

(3) Subject Matter: Cardiac Catheterization (Comprehensive)

(a) Comment: Kevin Halter, on behalf of Our Lady of Bellefonte Hospital, requests that the Cabinet lower the diagnostic cardiac catheterization threshold necessary to justify a new therapeutic cardiac catheterization program from 800 annual procedures to 400 annual procedures.

(b) Response: The Cabinet has considered this comment and believes that an entity should only be approved to establish a comprehensive cardiac catheterization program if they can either document a history of successfully providing primary PCI services or if they are currently operating a high volume diagnostic cardiac catheterization program. These standards are consistent with the recommendations contained in the Cabinet's recently sponsored statistical report entitled *Kentucky Pilot Project for Primary PCI without Onsite CABG* published by the University of Louisville's Cardiovascular Innovation Institute. Therefore, the Cabinet will not amend the State Health Plan to lower the diagnostic cardiac

catheterization volume threshold to a level below what was recommended in the above referenced report. Doing so could have a detrimental effect of the health, safety and welfare of potential patients.

(c) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, requests that the following changes be made:

1. The Cabinet should revise the definition of a "comprehensive" program to clarify that the provision of therapeutic cardiac catheterization services refers to those provided on both on an emergency basis and an elective basis;
2. The Cabinet should lower the diagnostic cardiac catheterization threshold necessary to justify a new therapeutic cardiac catheterization program from 800 annual procedures to 200 annual procedures while requiring an applicant to demonstrate an unmet need for an additional 200 annual PCI procedures;
3. The Cabinet should include a peer review requirement for the first 150 cases including both primary and elective cases;
4. The Cabinet should reduce the minimum volume threshold from 400 therapeutic cardiac catheterization procedures to 200 procedures;
5. The Cabinet should delete criteria 7 which requires cardiac catheterization laboratories only be used for catheterization and angiographic studies; and eliminate review criteria 3(g) which provides case selection standards for primary angioplasty. Both Bruce Begley, on behalf of Methodist Hospital and Andy Sears, on behalf of Baptist Healthcare System, support these recommendations.

(d) Response: The Cabinet has considered these comments and the State Health Plan has been amended to include comments 1, 3, and 5.

2. The State Health Plan has been amended to require an applicant to document the need for an additional 200 cardiac catheterization procedures but has not been amended to lower the diagnostic cardiac catheterization volume threshold from 800 annual procedures to 200 annual procedures, see comment 3 (a) and corresponding response.
4. The State Health Plan has been amended to require that the facility must demonstrate an additional need of two hundred (200) procedures, with an ideal volume of 400 procedures by the second year of operation.

(4) Subject Matter: Cardiac Catheterization (Mobile)

(a) Comment: Hollie Phillips, on behalf of Appalachian Regional Healthcare, requests that the Cabinet include a provision which would allow the establishment of a mobile cardiac catheterization service if all existing fixed site and mobile diagnostic cardiac catheterization laboratories within 50 minutes driving time performed 500 diagnostic procedures during the last 12 months and all comprehensive cardiac catheterization laboratories within 50 minutes driving time performed 1,100 diagnostic equivalent procedures during the last 12 months.

(b) Response: The Cabinet has considered this comment and the language which was previously included in the State Health Plan will be reinstated with the following changes: the distance will be 50 highway miles, 500 diagnostic procedures is reduced to 250 procedures, and 1100 diagnostic equivalent procedures is changed to 550 procedures. The planning area will also be changed from the ADD to the proposed county and all contiguous counties.

(c) Comment: Kelly Elkins, on behalf of Saint Joseph Health System, requests that the Cabinet re-establish the mobile cardiac catheterization review criteria contained in the *2009 Update to the 2007-2009 State Health Plan* except amend the service area to include 50 highway miles and lower the procedure thresholds.

(d) Response: The Cabinet has considered this comment. Please see the previous comment and corresponding response.

(e) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, requests that the Cabinet include a provision which would allow the establishment of a mobile cardiac catheterization service if all existing fixed site and mobile diagnostic cardiac catheterization laboratories within 50 minutes driving time performed 500 diagnostic procedures during the last 12 months and all comprehensive cardiac catheterization laboratories within 50 minutes driving time performed 1,100 diagnostic equivalent procedures during the last 12 months.

(f) Response: The Cabinet has considered this comment. Please see response b above.

(5) Subject Matter: Home Health

(a) Comment: Lisa Hinkle, on behalf of Nurses Registry, is displeased with the existing review criteria but offered no suggestions for improvement.

(b) Response: The Cabinet has considered this comment and will not be amending the home health criteria at this time, but may consider changes in the future.

(6) Subject Matter: ICF MR/DD

(a) Comment: Heidi Schissler Lanham, on behalf of Protection & Advocacy, requests that the Cabinet prohibit the transfer of public ICF MR/DD beds to private ICF MR/DD facilities.

(b) Response: The Cabinet has considered this comment but will not amend the State Health Plan at this time. The existing review criteria provide the Cabinet with the flexibility necessary to transfer public ICF MR/DD beds to private ICF MR/DD facilities without increasing the total number of ICF MR/DD beds available statewide.

(7) Subject Matter: Level II Psychiatric Residential Treatment Facilities

(a) Comment: Heidi Schissler Lanham, on behalf of Protection & Advocacy, requests that the Cabinet establish State Health Plan review criteria for Level II PRTF pursuant to HB 231.

(b) Response: The Cabinet has considered this comment and will solicit input from the Office of Health Policy, Department for Medicaid Services, and Office of Inspector General prior to promulgating an emergency regulation related to HB 231. The emergency regulations will be available for public review in August and will be filed with the LRC in October 2010.

(c) Comment: Michelle Sanborn, on behalf of the Children's Alliance, requests that the Cabinet delete regionalized target distribution for PRTF beds and establish State Health Plan review criteria for Level II PRTF pursuant to HB 231.

(d) Response: The Cabinet has considered this comment and will solicit input from the Office of Health Policy, Department for Medicaid Services, and

Office of Inspector General prior to promulgating an emergency regulation related to HB 231. The emergency regulations will be available for public review in August and will be filed with the LRC in October 2010.

(8) Subject Matter: Magnetic Resonance Imaging

(a) Comment: Nancy Galvagni, on behalf of the Kentucky Hospital Association, Bruce Begley, on behalf of Methodist Hospital, Andy Sears, on behalf of Baptist Healthcare System, and John Dubis on behalf of St. Elizabeth Healthcare support the existing MRI review criteria in the State Health Plan.

(b) Response: The Cabinet has considered this comment and we appreciate the support.

(9) Subject Matter: Psychiatric Hospital Beds

(a) Comment: Heidi Schissler Lanham, on behalf of Protection & Advocacy, requests that the Cabinet prevent an increase in the number of inpatient psychiatric hospital beds.

(b) Response: The Cabinet has considered this comment and will not be making any changes to the psychiatric hospital bed review criteria.

(10) Subject Matter: Special Care Neonatal Beds

(a) Comment: Mary Jo Bean, on behalf of Norton Healthcare, requests that the Cabinet incorporate the special care neonatal bed definitions from the most recent edition of the *Guidelines for Perinatal Care.*

(b) Response: The Cabinet has considered this comment and will not be making any changes to the neonatal review criteria at this time.

(c) Comment: Kelly Elkins, on behalf of Saint Joseph Health System, requests that the Cabinet incorporate the special care neonatal bed definitions from the most recent edition of the *Guidelines for Perinatal Care* and include provisions that would allow the conversion of existing Level II beds to Level III A beds.

(d) Response: The Cabinet has considered this comment and will not be making

any changes to the neonatal review criteria at this time.

(e) Comment: John Dubis, on behalf of St. Elizabeth Healthcare requests that the Cabinet incorporate the most current Perinatal Guidelines by the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists and supports the concept of differentiated categories of care within Level III defined by the Perinatal Guidelines as Level III A, B, or C.

(f) Response: The Cabinet has considered this comment and will not be making any changes to the neonatal review criteria at this time.

Summary of Statement of Consideration and
Action Taken by Promulgating Administrative Body

The Office of Health Policy is amending this administrative regulation in response to public comments received.

Page 1
Section 2(1)
Line 18

After "State Health Plan" insert as amended July 15, 2010

SUMMARY OF CHANGES TO INCORPORATED MATERIAL

The 2010-2010 State Health Plan is being incorporated by reference. The 2010-2012 State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a.

a. The revisions to the plan as a result of comments are the following:
   - Various grammatical and formatting changes were made throughout the document at the request of LRC staff.
   - The cover page edition date has been changed to July 14, 2010.
   - Page iii under the heading "Purpose, Authority and Technical Notes" KRS 216B.015(20)(a) was replaced with KRS 216B.015(28) and KRS 216B.015(26) was replaced with KRS 216B.015(27).
   - Page 6 under the subheading "Acute Care Beds", criteria 5 was deleted.
   - Pages 29 through 36 under the subheading "Cardiac Catheterization Service" were modified to:
     i. Restrict the establishment of fixed-site diagnostic cardiac catheterization laboratories to acute care hospitals.
     ii. Replace the *Kentucky Annual Hospital Utilization and Services Report* with the *Kentucky Annual Administrative Claims Data Report.*
     iii. Reduce the minimum volume threshold to establish a diagnostic cardiac catheterization laboratory.
     iv. Required each applicant to document the availability of at least 2 board certified cardiologist with medical staff privileges at the applicant's hospital.
     v. Expand the number of cardiac surgery facilities that are eligible to sign a collaboration agreement with a an applicant proposing to expand their existing diagnostic cardiac catheterization service to also provide primary PCI services on a two year trial basis.
     vi. Require that applicants proposing to expand their existing diagnostic cardiac catheterization service to also provide therapeutic cardiac catheterization services on a two year trial basis shall under peer review for the first 150 therapeutic cardiac catheterization procedures.
     vii. Establish need criteria for applicants proposing to provide comprehensive cardiac catheterization services.
     viii. Establish review criteria for applicants proposing to establish mobile adult diagnostic cardiac catheterization services.
     ix. Removed the restriction that cardiac catheterization laboratories shall be used only for catheterization and angiographic studies.
     x. Deleted repetitive references to individual physician volume.

   - Page 45 under the subheading "Ambulance Service" KRS 211.952 was replaced with KRS 311A.030.

b. The total number of pages incorporated by reference in the administrative regulation is fifty-four (54).